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ATTORNEY DOCKET NO. 21101.0046U2
PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of |) | |
| |) | |
| Gesteland, et al. |) | Art Unit: 1634 |
| |) | |
| Application No. 10/583,198 |) | Examiner: Unassigned |
| |) | |
| Filing Date: 11/15/2004 |) | Confirmation No. 2204 |
| |) | |
| For: METHODS, ARTICLES, AND |) | |
| COMPOSITIONS FOR IDENTIFYING |) | |
| OLIGONUCLEOTIDES |) | |

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. §1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(3), in that a first Office Action on the merits of the present patent application has not yet been mailed to Applicants.

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Application No. 10/583,198

In accordance with the provisions of M.P.E.P. § 2001.06(b) and 37 C.F.R. § 1.98(b)(3), Applicants would like to bring to the attention of the Examiner the existence of the co-pending patent applications identified below, which were filed in the United States Patent and Trademark Office:

| | <u>Application No.</u> | <u>Date Filed</u> | <u>Inventors</u> | <u>Attorney Docket No.</u> |
|----|-------------------------------|--------------------------|-------------------------|-----------------------------------|
| 1. | *10/374,253 | February 26, 2003 | Matveeva et al. | 21101.0059U2 |

The pending applications identified with an asterisk (*) above are stored in the Image File Wrapper (IFW) system of the USPTO. Accordingly, copies of the cited specifications, which includes the claims and drawings thereof, are not enclosed in accordance with the waiver to 37 CFR 1.98(a)(2)(iii) dated September 21, 2004.

For applications 10/374,253, the following prosecution documents are enclosed for the Examiner's consideration.

| For Appl. *10/374,253 | | |
|------------------------------|-------------------------------------|--------------------------------|
| <u>Date of Action</u> | <u>Type of Action</u> | <u>Date of Response</u> |
| 09-02-2005 | Restriction Requirement | |
| | Response to Restriction Requirement | 10-05-2005 |
| 11-21-2005 | Office Action | |
| | Response to Office Action | 05-22-2006 |
| 08-11-2006 | Office Action | |
| | Response to Office Action | 12-11-2006 |


Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

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No fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.


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Registration No. 57,896

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.


P. Brian Giles

1/3/07
Date



INFORMATION DISCLOSURE STATEMENT LIST

(Use as many sheets as necessary)

Complete if Known

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|----------------------|------------|
| Application Number | 10/583,198 |
| Filing Date | 11/15/2004 |
| First Named Inventor | Gesteland |
| Group Art Unit | 1634 |
| Examiner Name | Unassigned |

U.S. PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Document No. | Date | Name | Class | Subclass | Filing Date (if appropriate) |
|---------------------|----------|--------------|------------|----------|-------|----------|------------------------------|
| | A1 | 5,399,491 | 03-02-1995 | Kacian | | | |
| | A2 | 6,251,588 | 06-26-2001 | Shannon | | | |
| | A3 | 5,700,637 | 12-23-1997 | Southern | | | |
| | A4 | 5,667,667 | 09-16-1997 | Southern | | | |
| | A5 | 2003/0130802 | 07-10-2003 | Mei | | | |

FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Foreign Patent Document Country Code-Number-Kind Code | Date | Name | Translation Yes/No |
|---------------------|----------|--|------|------|-----------------------|
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NON-PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication) |
|---------------------|----------|---|
| | A6 | Allawi, H.T. and SantaLucia, J., Jr (1997) Thermodynamics and NMR of internal G-T mismatches in DNA. Biochemistry, 36, 10581-10594. |
| | A7 | Allawi, H.T. and SantaLucia, J., Jr (1998) Nearest neighbor thermodynamic parameters for internal G.A mismatches in DNA. Biochemistry, 37, 2170-2179. |
| | A8 | Allawi, H.T. and SantaLucia, J., Jr (1998) Nearest-neighbor thermodynamics of internal A.C mismatches in DNA: sequence dependence and pH effects. Biochemistry, 37, 9435-9444. |
| | A9 | Allawi, H.T. and SantaLucia, J., Jr (1998) Thermodynamics of internal C.T mismatches in DNA. Nucleic Acids Res., 26, 2694-2701. |
| | A10 | Amann, R.I., Ludwig, W. and Schleifer, K.H. (1995) Phylogenetic identification and in situ detection of individual microbial cells without cultivation. Microbiol Rev, 59, 143-169. |
| | A11 | Arnold, L.J., Jr., Hammond, P.W., Wiese, W.A. and Nelson, N.C. (1989) Assay formats involving acridinium-ester-labeled DNA probes Clin Chem, 35, 1588-1594. |
| | A12 | Chew, C.B., Zheng, F., Byth, K., Van Asten, M., Workman, C. and Dwyer, D.E. (1999) Comparison of three commercial assays for the quantification of plasma HIV-1 RNA from individuals with low viral loads [letter] Aids, 13, 1977-1978. |
| | A13 | Compton, J. (1991) Nucleic acid sequence-based amplification Nature, 350, 91-92. |
| | A14 | Debyser, Z., Van Wijngaerden, E., Van Laethem, K., Beuselinck, K., Reynders, M., De Clercq, E., Desmyter, J. and Vandamme, A.M. (1998) Failure to quantify viral load with two of the three commercial methods in a pregnant woman harboring an HIV type 1 subtype G strain AIDS Res Hum Retroviruses, 14, 453-459. |
| | A15 | DeLong, E.F., Wickham, G.S. and Pace, N.R. (1989) Phylogenetic stains: ribosomal RNA-based probes for the identification of single cells Science, 243, 1360-1363. |

Examiner Signature:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/583,198 |
| | | Filing Date | 11/15/2004 |
| | | First Named Inventor | Gesteland |
| | | Group Art Unit | 1634 |
| | | Examiner Name | Unassigned |

| | | |
|--|-----|---|
| | A16 | Ding,Y. and Lawrence,C.E. (2001) Statistical prediction of single-stranded regions in RNA secondary structure and application to predicting effective antisense target sites and beyond. Nucleic Acids Res., 29, 1034–1046. |
| | A17 | Dopazo, J., Rodriguez, A., Saiz, J.C. and Sobrino, F. (1993) Design of primers for PCR amplification of highly variable genomes Comput Appl Biosci, 9, 123-125. |
| | A18 | Gaschen, B., Kuiken, C., Korber, B. and Foley, B. (2001) Bioinformatics, 17, 415-418. |
| | A19 | Gibbs, A., Armstrong, J., Mackenzie, A.M. and Weiller, G.F. (1998) The GPRIME package: computer programs for identifying the best regions of aligned genes to target in nucleic acid hybridisation-based diagnostic tests, and their use with plant viruses J Virol Methods, 74, 67-76. |
| | A20 | Giddings,M.C., Matveeva,O.V., Atkins,J.F. and Gesteland,R.F. (2000) ODNBase—a web database for antisense oligonucleotide effectiveness studies. Oligodeoxynucleotides. Bioinformatics, 16, 843–844. |
| | A21 | Higgins, D.G. and Sharp, P.M. (1988) CLUSTAL: a package for performing multiple sequence alignment on a microcomputer. Gene, 73, 237-244. |
| | A22 | Jayaraman,A., Walton,S.P., Yarmush,M.L. and Roth,C.M. (2001) Rational selection and quantitative evaluation of antisense oligonucleotides. Biochim. Biophys. Acta, 1520, 105–114. |
| | A23 | Kel, A., Ptitsyn, A., Babenko, V., Meier-Ewert, S. and Lehrach, H. (1998) A genetic algorithm for designing gene family-specific oligonucleotide sets used for hybridization: the G protein-coupled receptor protein superfamily Bioinformatics, 14, 259-270. |
| | A24 | Lehmann,M.J., Patzel,V. and Sczakiel,G. (2000) Theoretical design of antisense genes with statistically increased efficacy. Nucleic Acids Res., 28, 2597–2604. |
| | A25 | Lucas, K., Busch, M., Mossinger, S. and Thompson, J.A. (1991) An improved microcomputer program for finding gene- or gene family- specific oligonucleotides suitable as primers for polymerase chain reactions or as probes Comput Appl Biosci, 7, 525-529. |
| | A26 | Luebke,K.J., Balog,R.P. and Garner,H.R. (2003) Prioritized selection of oligodeoxyribonucleotide probes for efficient hybridization to RNA transcripts. Nucleic Acids Res., 31, 750–758. |
| | A27 | Mathews,D.H., Burkard,M.E., Freier,S.M., Wyatt,J.R. and Turner,D.H. (1999) Predicting oligonucleotide affinity to nucleic acid targets. RNA, 5, 1458–1469. |
| | A28 | Matveeva,O.V., Shabalina,S.A., Nemtsov,V.A., Tsodikov,A.D., Gesteland,R.F. and Atkins,J.F. (2003) Thermodynamic calculations and statistical correlations for oligo-probes design. Nucleic Acids Res., 31, 4211–4217. |
| | A29 | Matveeva OV, Mathews DH, Tsodikov AD, Shabalina SA, Gesteland RF, Atkins JF, Freier SM. Thermodynamic criteria for high hit rate antisense oligonucleotide design. Nucleic Acids Res. 2003 Sep 1;31(17):4989-94 |
| | A30 | Matveeva OV, Foley BT, Nemtsov VA, Gesteland RF, Matsufuji S, Atkins JF, Ogurtsov AY, Shabalina SA. Identification of regions in multiple sequence alignments thermodynamically suitable for targeting by consensus oligonucleotides: application to HIV genome. BMC Bioinformatics. 2004 Apr 29;5:44 |

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| | | | Examiner Name | Unassigned |
| A31 | | Matveeva OV, Tsodikov AD, Giddings M, Freier SM, Wyatt JR, Spiridonov AN, Shabalina SA, Gesteland RF, Atkins JF. Identification of sequence motifs in oligonucleotides whose presence is correlated with antisense activity. Nucleic Acids Res. 2000 Aug 1;28(15):2862-5 | | |
| A32 | | Petersheim and Turner. Biochemistry. 1983. 22:256-263. | | |
| A33 | | Patzel,V., Steidl,U., Kronenwett,R., Haas,R. and Sczakiel,G. (1999) A theoretical approach to select effective antisense oligodeoxyribonucleotides at high statistical probability. Nucleic Acids Res., 27, 4328-4334. | | |
| A34 | | Peyret,N., Seneviratne,P.A., Allawi,H.T. and SantaLucia,J.,Jr (1999) Nearest-neighbor thermodynamics and NMR of DNA sequences with internal A.A, C.C, G.G, and T.T mismatches. Biochemistry, 38, 3468-3477. | | |
| A35 | | Proutski, V. and Holmes, E.C. (1996) Primer Master: a new program for the design and analysis of PCR primers Comput Appl Biosci, 12, 253-255. | | |
| A36 | | SantaLucia,J.,Jr (1998) A unified view of polymer, dumbbell and oligonucleotide DNA nearest-neighbor thermodynamics. Proc. Natl Acad. Sci. USA, 95, 1460-1465. | | |
| A37 | | SantaLucia,J.,Jr, Allawi,H.T. and Seneviratne,P.A. (1996) Improved nearest-neighbor parameters for predicting DNA duplex stability. Biochemistry, 35, 3555-3562. | | |
| A38 | | Scherr,M., Rossi,J.J., Sczakiel,G. and Patzel,V. (2000) RNA accessibility prediction: a theoretical approach is consistent with experimental studies in cell extracts. Nucleic Acids Res., 28, 2455-2461. | | |
| A39 | | Sczakiel G. eoretical and experimental approaches to design effective antisense oligonucleotides. Front Biosci. 2000 Jan 1;5:D194-201. | | |
| A40 | | Sczakiel,G. and Tabler,M. (1997) Computer-aided calculation of the local folding potential of target RNA and its use for ribozyme design. Methods Mol. Biol., 74, 11-15. | | |
| A41 | | Sohail,M. and Southern,E.M. (2001) Using oligonucleotide scanning arrays to find effective antisense reagents. Methods Mol. Biol., 170, 181-199. | | |
| A42 | | Sohail,M., Akhtar,S. and Southern,E.M. (1999) The folding of large RNAs studied by hybridization to arrays of complementary oligonucleotides. RNA, 5, 646-655. | | |
| A43 | | Sohail,M., Hochegger,H., Klotzbucher,A., Guellec,R.L., Hunt,T. and Southern,E.M. (2001) Antisense oligonucleotides selected by hybridization to scanning arrays are effective reagents in vivo. Nucleic Acids Res., 29, 2041-2051. | | |
| A44 | | Southern,E., Mir,K. and Shchepinov,M. (1999) Molecular interactions on microarrays. Nature Genet., 21, 5-9. | | |
| A45 | | Southern,E.M. (2001) History and overview. Methods Mol. Biol., 170, 1-15. | | |
| A46 | | Southern,E.M., Case-Green,S.C., Elder,J.K., Johnson,M., Mir,K.U., Wang,L. and Williams,J.C. (1994) Arrays of complementary oligonucleotides for analyzing the hybridization behavior of nucleic acids. Nucleic Acids Res., 22, 1368-1373. | | |

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| Examiner Name | Unassigned |

| | |
|-----|---|
| A47 | Sugimoto,N., Nakano,S., Katoh,M., Matsumura,A., Nakamuta,H., Ohmichi,T., Yoneyama,M. and Sasaki,M. (1995) Thermodynamic parameters to predict stability of RNA/DNA hybrid duplexes. Biochemistry, 34, 11211-11216. |
| A48 | Urdea, M.S. (1994) Branched DNA signal amplification. Biotechnology (NY), 12, 926-928. |
| A49 | Urdea, M.S., Wilber, J.C., Yeghiazarian, T., Todd, J.A., Kern, D.G., Fong, S.J., Besemer, D., Hoo, B., Sheridan, P.J., Kokka, R. et al. (1993) Direct and quantitative detection of HIV-1 RNA in human plasma with a branched DNA signal amplification assay Aids, 7 Suppl 2, S11-14. |
| A50 | Walker, G.T., Fraiser, M.S., Schram, J.L., Little, M.C., Nadeau, J.G. and Malinowski, D.P. (1992) Strand displacement amplification--an isothermal, in vitro DNA amplification technique Nucleic Acids Res, 20, 1691-1696. |
| A51 | Walker, G.T., Little, M.C., Nadeau, J.G. and Shank, D.D. (1992) Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system Proc Natl Acad Sci U S A, 89, 392-396. |
| A52 | Walton,S.P., Stephanopoulos,G.N., Yarmush,M.L. and Roth,C.M. (1999) Prediction of antisense oligonucleotide binding affinity to a structured RNA target. Biotechnol. Bioeng., 65, 1-9. |
| A53 | Walton,S.P., Stephanopoulos,G.N., Yarmush,M.L. and Roth,C.M. (2002) Thermodynamic and kinetic characterization of antisense oligodeoxynucleotide binding to a structured mRNA. Biophys. J., 82, 366-377. |
| A54 | Williams,J.C., Case-Green,S.C., Mir,K.U. and Southern,E.M. (1994) Studies of oligonucleotide interactions by hybridization to arrays: the influence of dangling ends on duplex yield. Nucleic Acids Res., 22, 1365-1367. |
| A55 | Xia,T., SantaLucia,J.,Jr, Burkard,M.E., Kierzek,R., Schroeder,S.J., Jiao,X., Cox,C. and Turner,D.H. (1998) Thermodynamic parameters for an expanded nearest-neighbor model for formation of RNA duplexes with Watson-Crick base pairs. Biochemistry, 37, 14719-14735. |
| | |

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| SECTION I. DOCKETING OR ATTORNEY / AGENT / PARALEGAL / SECRETARY Completed By: Signature: <u>[Signature]</u> Date: <u>January 3, 2007</u> Printed Name: <u>Andreen T. Barrett</u> | | |
| Date Received / Atty. Para. Client / Matter Number & Application Serial No. | January 3, 2007 21101.00461U2 App. No. 10/583,198 DEH/PBG: atb | |
| Document(s) Filed | 1. Information Disclosure Statement (2 Pages) 2. Information Disclosure List (3 Pages) 3. Copies of Fifty (50) Cited References 4. Copies of Three (3) Cited Office Actions for Application No. 10/374,253 along with corresponding Response to each Office Action 5. Certificate of Mailing Dated January 3, 2007 | |
| SECTION II. OFFICE SERVICES OR ATTORNEY / AGENT / PARALEGAL / SECRETARY Completed By: Signature: _____ Date: _____ Printed Name: _____ | | |
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